

REMARKS

The present response is submitted in reply to the Office action which was issued on January 21, 2009. Claims 1-22 are pending in this application, each of which is subject to restriction as discussed below. By the present response, claim 3 has been amended for clarification purposes. No new matter has been added.

Claims 1-22 are pending in the instant application. The Examiner has concluded that restriction to one of the following groups is necessary:

- I. Claims 1-15 and 18-21 drawn to a film-shaped therapeutic system.
- II. Claims 16, 17 and 22, drawn to a process for medicinal therapy.

The Examiner explains in the Office action that the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features since the common technical feature among the inventions is the film-shaped therapeutic system comprising a polyacrylate layer and a polyvinyl alcohol layer, which is not a contribution over the prior art as evidenced by U.S. Patent No. 4,517,173 (Kizawa, et al.). The Examiner further states that Kizawa, et al. teach a mucous membrane-adhering film preparation consisting of two layers, one of which consists of pharmaceutical agents and a polymeric material (e.g., an acrylic acid polymer and polyvinyl alcohol). The Examiner still further states that the reference teaches that the preparations comprise a poorly water soluble layer. Therefore, the Examiner concludes that the film-shaped therapeutic system of the present invention is disclosed by Kizawa, et al.

The Applicant objects to the instant restriction requirement, with traverse. It is respectfully submitted that Kizawa, et al. fail to teach a mucoadhesive layer comprising a hydrophilic, mucoadhesive polymer which is dispersed in a polymer matrix based on polyvinyl alcohols. Although Kizawa, et al. in column 3 teach “water soluble high polymers” such as acrylic acid copolymers and polyvinyl alcohol, Kizawa, et al. fail to identify any “hydrophilic, mucoadhesive polymers.” Therefore, Kizawa, et al. fail to disclose a mucoadhesive layer comprising a combination of polymers as presently claimed.

The above notwithstanding, the Applicant hereby elects the claims of Group I (which reads on claims 1-15 and 18-21, drawn to a film-shaped therapeutic system) for further prosecution on the merits thereof. The Applicant further elects poly(methyl vinyl ether maleic anhydride) from the hydrophilic mucoadhesive polymers recited in claim 3, which is dependant from claim 1. It is noted that the present election is in accordance with paragraph [000018] of the present specification, as well as the embodiment in which “GANTREZ®” S 95 is used as a mucoadhesive polymer. As indicated in paragraph [000018], the trade name GANTREZ® relates to poly(methyl vinyl ether maleic anhydride) and its aqueous or alcoholic hydrolysates and salts. Therefore, it is respectfully requested that the species election set forth above should further include “aqueous hydrolysates of poly(methyl vinyl ether maleic anhydride), alcoholic hydrolysates of poly(methyl vinyl ether maleic anhydride) and salts of poly(methyl vinyl ether maleic anhydride), in accordance with claim 3.

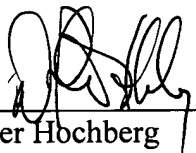
Regarding the number of layers, the Applicant hereby elects 2 layers.

The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: February 23, 2009

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